The following corrections or additions to the January 2003 list were published in the Federal Register in July 2003.

New Approvals

NADA Number: 141-181

Trade Name:	Avatec® / Albac®
Ingredients:	Lasalocid, bacitracin zinc
Sponsor:	Alpharma, Inc.
Approval Date:	May 15, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Turkeys, growing
Drug Form:	Type A Medicated Articles to make Type C medicated feeds.
Concentration:	Lasalocid – 90.7 grams activity per pound of Type A Medicated Article; bacitracin zinc – 50 grams activity per pound of Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis,* and *E. adenoeides*, for increased rate of weight gain and improved feed efficiency.
Tolerance:	*21CFR 556.70* Bacitracin: A tolerance for residues of bacitracin zinc or bacitracin methylene disalicylate has been established at 0.5 part per million in uncooked edible tissues. *21CFR 556.347* Lasalocid: The tolerance for parent lasalocid (marker residue) in liver and skin with adhering fat is 0.4 part per million.
Withdrawal:	Zero days

21CFR 558.78 & 558.311

NADA Number: 141-213

Trade Name:	Metacam®
Ingredients:	Meloxicam
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.
Approval Date:	April 15, 2003
Status:	Prescription only
Route:	Oral
Species:	Dogs
Drug Form:	Liquid (suspension)
Concentration:	0.5 or 1.5 milligrams per milliliter
Indications:	For the control of pain and inflammation associated with osteoarthritis.
Patent Number:	6,184,220 Expiration date: February 6, 2021
Exclusivity:	5 years

21CFR 520.1350

ANADA Number: 200-208

Pioneer Product:	126-052
Trade Name:	Avatec® / 3-Nitro® / Albac®
Ingredients:	Lasalocid sodium, roxarsone, bacitracin zinc
Sponsor:	Alpharma, Inc.
Approval Date:	June 24, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Chickens, broilers
Drug Form:	Type A Medicated Articles to make Type C medicated feeds.
Concentration:	Lasalocid – 3.0, 3.3, 3.8, 4.0, 4.3, 4.4, 5.0, 5.1, 5.5, 5.7, 6.0, 6.3, 6.7, 7.2, 7.5, 8.0, 8.3, 10.0, 12.5, 15, 20, or 50 percent activity per pound of Type A Medicated Article; Roxarsone – 10, 20, 50, or 80 percent activity per pound of Type A Medicated Article; Bacitracin zinc – 50 percent activity per pound of Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. maxima*, *E. necatrix*, *E. tenella*, *E. mivati,* and *E. brunette;* as an aid in the reduction of lesions due to *E. tenella;* for increased rate of weight gain and for improved feed efficiency.
Tolerance:	*21 CFR 556.60* Arsenic (roxarsone): Tolerances for residues are established at 0.5 part per million in uncooked muscle tissue and eggs and 2 parts per million in uncooked edible by-products. *21CFR 556.70* Bacitracin: A tolerance for residues of bacitracin zinc or bacitracin methylene disalicylate has been established at 0.5 part per million in uncooked edible tissues. *21 CFR 556.347* Lasalocid: The tolerance for parent lasalocid (marker residue) in skin with adhering fat is 1.2 parts per million.
Withdrawal:	5 days

21CFR 558.78, 558.311, & 558.530

ANADA Number: 200-266

Pioneer Product:	116-087
Trade Name:	Butequine®
Ingredients:	Phenylbutazone
Sponsor:	Bioniche Animal Health USA, Inc.
Approval Date:	February 21, 2003
Status:	Prescription only
Route:	Oral
Species:	Horses
Drug Form:	Paste
Concentration:	20 grams per 60 milliliter syringe (1 gram per 3 milliliters)
Indications:	For the relief of inflammatory conditions associated with musculoskeletal system.

21CFR 520.1720c

ANADA Number: 200-287

Pioneer Product:	140-896
Trade Name:	GBC Ointment™
Ingredients:	Gentamicin sulfate, betamethasone valerate, clotrimazole
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	March 28, 2003
Status:	Prescription only
Route:	Topical
Species:	Dogs
Drug Form:	Ointment
Concentration:	Each gram contains 3 milligrams gentamicin base, 1 milligram betamethasone, and 10 milligrams clotrimazole
Indications:	For the treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin

21CFR 524.1044g

ANADA Number: 200-323

Pioneer Product:	099-618
Trade Name:	Phenylbutazone Tablets
Ingredients:	Phenylbutazone
Sponsor:	West-Ward Pharmaceutical Corp.
Approval Date:	March 28, 2003
Status:	Prescription only
Route:	Oral
Species:	Horses, not to be used for food
Drug Form:	Tablet
Concentration:	1 gram per tablet
Indications:	For relief of inflammatory conditions associated with the musculoskeletal system.

21CFR 520.1720a & 510.600

ANADA Number: 200-355

Pioneer Product:	140-867
Trade Name:	Pennchlor™ / Bio-Cox® / 3-Nitro®
Ingredients:	Chlortetracycline, salinomycin sodium, roxarsone
Sponsor:	Pennfield Oil Company
Approval Date:	March 31, 2003
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Chickens, broilers
Drug Form:	Type A Medicated Articles to make Type C medicated feeds.
Concentration:	Chlortetracycline 50, 65, and 70 grams activity per pound in Type A Medicated Articles; Salinomycin 30 and 60 grams activity per pound in Type A Medicated Articles; Roxarsone 10, 20 and 50% (45.4, 90.8, 227 g/lb) activity per pound in Type A Medicated Articles .
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than salinomycin alone, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.
Tolerance:	*21CFR 556.150* Chlortetracycline: Tolerances for the sum of residues of the tetracycline, including chlortetracycline in tissues of chickens are: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat. *21CFR 556.60* Roxarsone: Tolerances of arsenic (from roxarsone) are established at 0.5 part per million in uncooked muscle tissue and 2 parts per million in uncooked edible by-products with liver as the target tissue. Salinomycin does not require a tolerance.
Withdrawal:	5 days

21CFR 558.550

Supplemental Approvals

NADA Number: 048-761

This supplemental application provides for use of a Type A Medicated Article to make Type B and C swine feeds for the control of porcine proliferative enteropathies (ileitis).

Trade Name:	Aureomycin® 50, 90, or 100 Granular
Ingredients:	Chlortetracycline
Sponsor:	Alpharma, Inc.
Approval Date:	November 15, 2001
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Swine
Drug Form:	Type A Medicated Article to make Type B and C medicated feeds.
Concentration:	Chlortetracycline 50, 90, or 100 grams activity per pound of Type A Medicated Article.
Indications:	Swine: For the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline, control of porcine proliferative enteropathy (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline, increased rate of weight gain and improved feed efficiency, and for reduction in the incidence of cervical lymphadenitis (jowl abscess) caused by Group E *Streptococci* susceptible to chlortetracycline. Breeding Swine: For the control of leptospirosis (reducing the incidence of abortion and shedding of *leptospirae*) caused by *Leptospira pomona.*
Tolerance:	*21CFR 556.150* Chlortetracycline: Tolerances are established for the sum of tetracycline residues in tissues of swine of 2 parts per million in muscle, 6 parts per million in liver and 12 parts per million in fat and kidney.
Withdrawal:	Zero days

21CFR 558.128

NADA Number: 140-865

This supplemental application provides for an alternate source of the bacitracin zinc.

Trade Name:	Monteban® / Albac®
Ingredients:	Narasin, bacitracin zinc
Sponsor:	Alpharma, Inc.
Approval Date:	April 29, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Chickens, broilers
Drug Form:	Type A Medicated Articles to make Type B and Type C medicated feeds.
Concentration:	Narasin – 36, 45, 54, 72 or 90 grams activity per pound of Type A Medicated Article; bacitracin zinc – 50 grams activity per pound of Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by E*imeria acervulina*, *E. maxima*, *E. necatrix*, *E. tenella*, *E. mivati,* and *E. brunetti* and for increased rate of weight gain and improved feed efficiency.
Tolerance:	*21CFR 556.70* Bacitracin: A tolerance for residues of bacitracin zinc or bacitracin methylene disalicylate has been established at 0.5 part per million in uncooked edible tissues. *21CFR 556.428* Narasin: A tolerance for residues in chickens is not needed.
Withdrawal:	Zero days

21CFR 558.78 & 558.363

NADA Number: 134-314

This supplemental application provides for the addition of several new species of internal parasites.

Trade Name:	Eqvalan® Paste
Ingredients:	Ivermectin
Sponsor:	Merial, Ltd.
Approval Date:	April 2, 2003
Status:	Over-the-counter
Route:	Oral
Species:	Horses
Drug Form:	Paste
Concentration:	1.87%
Indications:	For treatment and control of the parasites or parasitic conditions: **Large Strongyles** (adults): *Strongylus vulgaris* (and arterial larval stages), *S. edentatus* (and tissue stages), *S. equinu; Triodontophorus* spp. including *Triodontophorus brevicauda, Triodontophorus serratus;* ***Craterostomum acuticaudatum*** **Small Strongyles** (adults and fourth-stage larvae) (including those resistant to some benzimidazole class compounds): ***Coronocyclus*** spp. including ***Coronocyclus coronatus,*** *Coronocyclus labiatus****,*** ***Coronocyclus labratus;*** *Cyathostomum* spp. including *Cyathostomum catinatum, Cyathostomum pateratum; Cylicocyclus* spp. including *Cylicocyclus insigne, Cylicocyclus leptostomum, Cylicocyclus nassatus, Cylicocyclus brevicapsulatus; Cylicodontophorus* spp.; *Cylicostephanus* spp. including *Cylicostephanus calicatus, Cylicostephanus goldi, Cylicostephanus longibursatus, Cylicostephanus minutis;* ***Petrovinema poculatum***. **Pinworms** (adults and fourth-stage larvae): *Oxyuris equi* **Ascarids** (adults and third-and fourth-stage larvae): *Parascaris equorum* **Hairworms** (adults): *Trichostrongylus axei* **Large-Mouth Stomach Worms** (adults): *Habronema muscae* **Neck threadworms** (microfilariae): *Onchocerca* spp. **Bots** (oral and gastric stages): *Gastrophilus* spp. including *G. intestinalis* and *G. nasalis* **Lungworms** (adults and fourth-stage larvae): *Dictyocaulus arnfieldi* **Intestinal Threadworms** (adults): *Strongyloides westeri* **Summer Sores**: caused by *Habronema and Draschia* spp. cutaneous third-stage larvae.
Exclusivity:	3 years

21CFR 520.1192

NADA Number: 141-025

This supplemental application provides for the establishment of a tolerance for residues of laidlomycin.

Trade Name:	Cattlyst®
Ingredients:	Laidlomycin propionate potassium
Sponsor:	Alpharma, Inc.
Approval Date:	May 12, 2003
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle
Drug Form:	Type A Medicated Article
Concentration:	50 grams activity per pound of Type A Medicated Article
Indications:	For improved feed efficiency and increased rate of weight gain in cattle fed in confinement for slaughter.
Tolerance:	*21CFR 556.346* Laidlomycin: The Acceptable Daily Intake (ADI) for total residues is 7.5 micrograms per kilogram of body weight per day. The tolerance for parent laidlomycin (the marker residue) in the liver (the target tissue) is 0.2 part per million.
Withdrawal:	Zero days

21CFR 558.305 & 556.346

NADA Number: 200-144

This supplemental application provides for an additional pouch size.

Trade Name:	Tetroxy® HCA
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Cross Vetpharm Group Ltd.
Approval Date:	April 21, 2003

21CFR 520.1660

NADA Number: 200-219

This supplemental application provides for use of an ivermectin solution on cattle for control of certain internal parasites for 14 days after treatment.

Trade Name:	Phoenectin™ Pour-On for Cattle
Ingredients:	Ivermectin
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	May 16, 2001
Status:	Over-the-counter
Route:	Topical
Species:	Cattle
Drug Form:	Liquid (solution)
Concentration:	5 milligrams per milliliter
Indications:	For the treatment and control of the following parasites: Gastrointestinal roundworms (*Ostertagia ostertagi,* adult and fourth stage larvae including inhibited stage; *Haemonchus placei*, adults and fourth stage larvae; *Trichostrongylus axei*, adults and fourth stage larvae; *T. colubriformis*, adults and fourth stage larvae; *Cooperia spp.*, adults and fourth stage larvae; *Strongyloides papillosus*, adults; *Oesophagostomum radiatum*, adults and fourth stage larvae; *O. venulosum*, adults only; *Trichuris spp.*, adults: lungworms (*Dictyocaulus viviparus*, adults and fourth stage larvae); cattle grubs (*Hypoderma bovis, H. lineatum,* parasitic stages): mites (*Sarcoptes scabei var. bovis, Chorioptes bovis*): lice (*Linognathus vituli, Haematopinus eurysternus, Damalinia bovis, Solenoptes capillatus*): horn flies (*Haematobia irritans)*. For control of infections and to protect from re-infection with *Ostertagia ostertagi, O. radiatum, H. placei, T. axei, Cooperia punctata,* and *C. oncophora* for 14 days after treatment.
Tolerance:	*21CFR 556.344* Ivermectin: A tolerance is established for 22,23-dihydro-avermectin B1a in liver as 100 parts per billion and 10 parts per billion in muscle.
Withdrawal:	48 days

21CFR 524.1193

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 200-346

This supplemental application provides for the addition of tylosin tartrate as a local antibacterial to an approved subcutaneous implant containing trenbolone and estradiol.

Trade Name:	Component® TE-H with Tylan
Ingredients:	Trebolone acetate, estradiol, tylosin tartrate
Sponsor:	Ivy Laboratories
Approval Date:	April 18, 2003
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle, heifers fed in confinement for slaughter
Drug Form:	Implant
Concentration:	140 milligrams trenbolone acetate, 14 milligrams estradiol, and 29 milligrams tylosin per implant.
Indications:	For increased rate of weight gain and improved feed efficiency.
Tolerance:	*21CFR 556.240* Estradiol: Residues for estradiol and related esters may not exceed the following increments above the concentration of estradiol naturally present in untreated animals: In the uncooked edible tissues of heifers, steers, and calves: 120 parts per trillion in muscle, 480 parts per trillion in fat, 360 parts per trillion in kidney, and 240 parts per trillion in liver. *21CFR 556.739* Trenbolone: A tolerance for total residues in uncooked edible tissues of cattle is not needed. *21CFR 556.740* Tylosin: Tolerances are established for residues of tylosin in edible products of cattle as 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
Withdrawal:	Zero days
Exclusivity:	3 years

21CFR 522.2477

Addition of Sponsor

West-Ward Pharmaceutical, Inc.
Industrial Way West
Eatontown, NJ 07724
Labeler code: 000143

Change of Sponsor

NADA Numbers: 055-069, 055-070, 055-100

From:	Pfizer, Inc.
To:	Schering-Plough Animal Health Corp. 1095 Morris Ave. Union, NJ 07083
Drug labeler code:	000061

Actions Taken by FDA Center for Veterinary Medicine

Removal of a Patent

NADA Numbers: 038-878, 041-500, 047-933, 049-463, 049-464, 095-735, 104-646, 118-980, 119-823, 130-736, 138-952, 140-445, 140-926, 140-955, 141-164

Patent Number: 4,764,534
Expiration Date: August 16, 2005

Suitability Petition Action

Number: 03P-0219/CP1
Sponsor: Vetoquinol N.-A. Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, amoxicillin, which differs from the pioneer product, Robamox®-V (amoxicillin trihydrate), Teva Pharmaceuticals USA, NADA 065-495, by the following characteristics: The generic product will have a different dosage form (paste) and strength from the pioneer.
Action: Approved on July 31, 2003.

Number: 03P-0223/CP1
Sponsor: Richdel, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® (ivermectin) Liquid for Horses, Merial Ltd., NADA 140-439 by the following characteristic: The generic product will have a different dosage form (solubilized gel) from the pioneer.
Action: Approved on July 31, 2003.

Technical Amendment

The Food and Drug Administration is amending *21 CFR 522.900* to include warning statements on product labeling, informing that these products might be toxic to wildlife. This change is effective May 2, 2003.